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In this supplement: Managing ID threats at the federal level

What does the Public Health Agency of Canada (PHAC) do to manage infectious disease threats at the federal level? Quite a lot, actually. Find about the travel health notices and advice PHAC develops to inform Canadians on ways to help reduce risks when travelling abroad, how the Agency protects public health on passenger conveyances (e.g. planes and ships) and works with Border Services to screen for infectious diseases. Read about the new plan for Rapid Response Teams to help contain an emerging infectious disease outbreak. And learn about new regulations that, as of December 1, 2015 require licencing for those who possess, handle, produce, import, export, store, or dispose of a human pathogen or toxin.

Overview

Federal public health strategies to minimize the importation of communicable diseases into Canada 3
Bhatia N, Sarwal S, Robinson H, Geduld J, Huneault F, Schreiner H, Collins S, Hickey R

Implementation science

Ready to go! Canada's new Rapid Response Teams 9
Lior LY, Njoo H

Regulations

Regulatory oversight of human pathogens and toxins in Canada 14
Labrie C, Lecordier S

Notice of appreciation

Thank you to the CCDR peer reviewers of 2015 19

Useful links

Government of Canada. **Country travel advice and advisories.**
http://travel.gc.ca/travelling/advisories

Public Health Agency of Canada. **Laboratory Biosafety and Biosecurity.**
http://www.phac-aspc.gc.ca/lab-bio/faq-eng.php

News Flash

European Centre for Disease Prevention and Control. **Rapid Risk Assessment: Microcephaly in Brazil potentially linked to the Zika virus epidemic**
http://ecdc.europa.eu/en/publications/Publications/zika-microcephaly-Brazil-rapid-risk-assessment-Nov-2015.pdf

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Canada

Canada Communicable Disease Report

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Overview

Federal public health strategies to minimize the importation of communicable diseases into Canada

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Abstract

Background: The global spread of communicable diseases is a growing concern largely as a result of increased international travel. In Canada, although most public health management of communicable diseases occurs at the front line, the federal government also takes actions to prevent and mitigate their importation.

Objective: To describe the role of the Public Health Agency of Canada (PHAC) in minimizing the importation of communicable diseases through preventive measures taken before travellers leave Canada and through early detection and prompt containment measures taken when travellers arrive in the country with a potential communicable disease.

Interventions: PHAC works to minimize the importation of communicable diseases into Canada by developing evidence-based travel health advice and targeted outreach activities geared to the public and to health care professionals. On the basis of the *Quarantine Act* and the *International Health Regulations* (2005), PHAC also conducts inspections of conveyances such as aircraft and boats and works with partners to conduct border screening to assess ill travellers entering the country.

Conclusion: PHAC plays an important role in preventing and minimizing the importation of communicable diseases into Canada in conjunction with clinicians, public health authorities at all levels of government and other federal government departments.

Introduction

According to the World Bank, international travel has been steadily increasing and it is estimated that in 2011, international tourist arrivals exceeded one billion (1). The continuous movement of people and goods into Canada by air, land and sea has resulted in an ever-present risk of importing communicable diseases.

In Canada, communicable diseases are managed primarily at the provincial, territorial and local levels. However, many federal government departments are also involved in minimizing the importation of human and animal pathogens, toxins, vectors and reservoirs of communicable diseases (**Table 1**). There are extensive federal legislations that direct government departments to address this (2,3-8). For example, Acts and regulations administered by the Public Health Agency of Canada (PHAC) include the *Human Pathogens Importation Regulations* (2), the *Quarantine Act* (3) and the *Potable Water Regulations for Common Carriers* (4).

Table 1: Examples of activities by federal departments to minimize the importation of communicable diseases into Canada

Public Health Agency of Canada	Canadian Food Inspection Agency	Canada Border Services Agency	Citizenship and Immigration Canada
• Provide travel health advice and recommendations to individuals and health professionals. • Assess ill individuals at points of entry. • Inspect conveyances, ancillary services and terminals. • Regulate importation of human pathogens. • Contribute to the development and maintenance of core public health capacity to protect citizens from public health risks and is the national focal point for the *International Health Regulations*.	• Regulate the importation of food products. • Regulate the importation of plants and plant products. • Regulate the importation of live animals and animal products and by-products. • Inspect livestock at points of entry.	• Conduct initial screening of people, food, cargo, baggage and agricultural products at points of entry	• Screen immigrants and certain other classes of foreign nationals for selected infectious diseases prior to arrival in Canada.

The objective of this article is to provide an overview of PHAC's roles and responsibilities in minimizing the importation of communicable diseases into Canada through preventive measures taken for travellers and modes of transportation prior to leaving the country as well as measures taken when ill people enter the country. It does not include, nor is it meant to diminish, the roles of local, provincial and territorial authorities or other federal government departments.

The federal public health strategy

PHAC minimizes the importation of communicable diseases into Canada through preventive and response activities, aimed at travellers and modes of transportation. Travel health information is available to individuals before they leave the country. Conveyances, or international modes of transportation are inspected and public health risks are addressed. All travellers are screened on arrival to Canada. Other papers in this issue address how PHAC manages new legislation that sets out a risk-based licensing framework to improve federal oversight of human pathogens and toxins in Canada (9),and how PHAC can assist in the rapid response to manage and contain an infection when it does enter the country (10).

Minimizing risks before leaving Canada

PHAC provides travel health advice and recommendations to travellers and to health care professionals. Advice is also provided to conveyance operators. Inspections are conducted of conveyances, ancillary services (such as flight kitchens) and terminals.

Information for travellers

PHAC's Travel Health Program publishes travel health notices, travel-related disease fact sheets and travel health recommendations by destination on the PHAC website and travel.gc.ca (11). Travel health notices notify the public about health events including outbreaks that may be of concern to travellers. The notices provide a level of risk and recommend measures that can be taken by travellers (**Table 2**).

Table 2: Travel health notices and levels of risk

Risk level	Explanation	Example (when)
1. Practice usual precautions	• Advises travellers to practice usual precautions (e.g., routine vaccinations, hand washing, protective measures to avoid mosquito bites).	Chikungunya virus infection in the Caribbean (still current as of December 2015)
2. Practice enhanced precautions	• Recommends that travellers practice special precautions, such as receive additional vaccines. • Would be issued if there was an outbreak in a limited geographic location, a newly identified disease in the region, or a change in the existing pattern of disease.	World Health Organization (WHO) temporary polio vaccine recommendations (still current as of December 2015)
3. Avoid non-essential travel	• A warning to avoid non-essential travel in order to protect the health of Canadian travellers and the Canadian public. • Outlines specific precautions to take when visiting the region and what to do if you become ill during or after travel. • Would be issued during a large-scale outbreak in a large geographic area, or if there is increased risk to the traveller and an increased risk of spreading disease to other groups including the Canadian public.	Ebola virus disease in West Africa (still current in Guinea and Sierra Leone as of December 2015)
4. Avoid all travel	• Advises travellers to avoid all travel in order to protect the health of the Canadian public. • Would be issued if there is a high risk of spread of disease to the general public regardless of measures taken while travelling. Avoiding travel will limit the spread of the disease in Canada and internationally.	Never issued.

Information on measures to take during mass gathering events is also provided through targeted outreach. For example, specific information is provided to Canadians planning to attend the Hajj, the Muslim pilgrimage to Mecca, Saudi Arabia. During the Hajj, there is increased risk of transmission of certain communicable diseases, such as meningococcal meningitis and respiratory infections (12,13). Beginning in 2014, materials such as posters and information sheets were developed and translated into five languages (French, English, Arabic, Urdu and Turkish). These materials were distributed to stakeholders, including physicians and community centres in Muslim communities, mosques, Islamic schools and Canadian travel agencies authorized to issue visas for Hajj pilgrims. In 2014, these travel agencies issued approximately 3,500 visas to attend the Hajj.

Finally, during specific public health events such as the Severe Acute Respiratory Syndrome (SARS),pandemic H1N1, and more recently the Ebola outbreak in West Africa, information was provided to travellers in airports through posters and on airport monitors (14). Travel health information was also available on the travel.gc.ca website (11) and through social media, such as Facebook and Twitter.

Information for health professionals

PHAC provides secretariat and epidemiologic support to the Committee to Advise on Tropical Medicine and Travel (CATMAT), an expert advisory body that assists PHAC in developing travel health recommendations for travellers and health professionals (15). CATMAT produces evidence-based recommendations on the prevention and treatment of infectious diseases and other health hazards that Canadian travellers may encounter internationally. CATMAT statements and recommendations on travel health diseases, conditions and special populations are available on the PHAC website.

Minimizing risk on conveyances

A conveyance is a mode of transportation such as aircraft, trains, cruise ships and ferries (4). PHAC's Travelling Public Program works with the international conveyance sector largely aircraft and ships. PHAC

conducts risk assessments of conveyances and ancillary services, including flight kitchens and terminals, and works with operators to correct any identified public health risks. Inspections focus on potable water, food, sanitation and vector control. Other activities include potable water sampling on conveyances under the *Potable Water Regulations for Common Carriers* (4) and food handler and sanitation training for industry employees.

The Travelling Public Program has a compliance inspection program for cruise ships that visit Canadian ports (16). Unannounced inspections are conducted on participating cruise ships travelling in Canadian waters. The scoring system is based on 41 inspection items with a total value of 100 points. A satisfactory score is 86 points out of a possible 100 points. A score of 85 or lower is not satisfactory and requires a re-inspection within the following month. An unsatisfactory score does not mean, however, that the travelling public is exposed to any imminent risk to his/her health.

Minimizing the importation of communicable diseases

In the *International Health Regulations* (2005) (IHR (2005), a point of entry is defined as a passage for international entry or exit for travellers, conveyances and goods and includes airports, marine ports and land crossings (17). Many of the public health measures taken at points of entry are conducted under the umbrella of the IHR (2005), an international treaty that Canada has signed (18). The purpose of the IHR (2005) is to prevent, protect against, control and respond to the international spread of disease while avoiding unnecessary interference with international traffic and trade. Under the IHR (2005), Canada is obligated to take health measures at points of entry in order to limit the spread of public health risks.

To determine whether Canada met IHR (2005) requirements at points of entry, the capacity to detect and respond to public health risks (including infectious diseases) was assessed at five points of entry. These points of entry were selected based on volume of travellers and geographic representation and included the Vancouver International Airport, Toronto Pearson International Airport, Montréal-Trudeau International Airport, Metro Vancouver Cruise Ship Terminal and the Halifax Cruise Ship Terminal. These points of entry met WHO requirements and are therefore considered designated points of entry under the IHR (2005). WHO requirements for designated points of entry include having staff and resources available to assess, care for and transport ill travellers and animals and the capacity to inspect conveyances and terminals for public health risks. Furthermore, these IHR-designated Canadian points of entry routinely conduct exercises to assess their response capacity and to ensure that they continue to meet IHR (2005) requirements.

Prior to arrival in Canada

Prior to entering Canadian waters, all international cruise ships report their gastrointestinal illness (GI) rates in passengers and crew to PHAC's Travelling Public Program. Immediate reporting is required if the GI illness rates are above key public health thresholds. PHAC works with the cruise ship operator to mitigate the risk to the other passengers or crew by ensuring the cruise ship has implemented its outbreak prevention procedures. PHAC environmental health officers, who are certified Public Health Inspectors, may conduct an onboard investigation.

Additionally, aircraft are required to report any illnesses or deaths on board to the airport authority prior to arrival. These cases are then assessed by PHAC quarantine officers, who are registered nurses (3).

Upon arrival in Canada

All travellers arriving in Canada are obligated to present themselves to a Canadian Border Services Agency officer where they are screened for illness as well as for any food, plant and animal products in their possession. As specified in the quarantine *Act*, if a traveller screens positive for a potential communicable disease that poses a public health risk, he/she is referred to a quarantine officer for further assessment, which includes a history and temperature check (3). Quarantine officers are stationed in selected airports across the country which have a high volume of international travellers. If the ill traveller arrives at one of these airports, this assessment is conducted in person. If the ill traveller is at a point of entry other than these airports, such as a marine port or a land crossing, this assessment is conducted by telephone.

If the quarantine officer suspects that the traveller has a communicable disease that poses a public health risk, certain measures can be taken, e.g., the traveller can be ordered to report to a nearby hospital for further evaluation or can be ordered to report to the local public health authority within a specified amount of time for follow-up. The Quarantine Officer will coordinate with the local public health authority, emergency services and the hospital to manage the ill traveller.

Environmental health officers also responds to incidents on board conveyances if food, water or sanitation is of concern. For example, environmental health officers may advise aircraft groomers on cleaning spills of body fluids or may investigate reports of vectors, such as rats on ships.

After arrival in Canada

PHAC provides financial support to the Canadian Travel Medicine Network (CanTravNet), a network of Canadian clinical experts in travel and tropical medicine (19). CanTravNet sites are members of the GeoSentinel Global Surveillance Network, an international network that collects data on returned travellers and immigrants as a sentinel network for global emerging infections.

When a serious infection or outbreak is identified, PHAC has the capacity to deploy a rapid response team to help local and provincial or territorial health authorities to assist in the protection of health care workers and to treat and limit the spread of the disease (18). Under the IHR (2005), information on certain public health events, including communicable diseases, may be shared with the World Health Organization to facilitate international collaboration during a public health response (17,18).

Discussion

PHAC has a strong federal public health strategy to minimize the importation of communicable diseases into Canada based on health promotion and prevention, early detection and prompt response. PHAC meets its mandate by working in close collaboration with clinical care and public health authorities from a local through to an international level, as well as with other federal departments such as the Canadian Border Services Agency and the Canadian Food Inspection Agency.

One of the components of PHAC's strategy is the entry border screening of travellers. Travellers are screened based on signs and symptoms, rather than laboratory testing. Upon arrival, travellers may be asymptomatic, either in the incubation period or have a subclinical infection, have mild symptoms, use antipyretics to reduce fever, or may not report their symptoms. Because cases may be missed, entry screening has been described as ineffective and resource-intensive (13,20-22). However, the efficacy of border screening is difficult to evaluate (23). One study has shown that entry screening may delay local transmission of a novel influenza strain by one to two weeks, time which could be used for further community preparation for an epidemic (21). In addition, visible border screening and control may increase public confidence, awareness and compliance. While entry screening of travellers at borders has limitations, it is only one piece of PHAC's strategy to minimize the importation of communicable diseases into Canada.

New infectious disease threats will continue to emerge in the context of globalization and increased travel, however an integrated system is in place to minimize the importation of communicable diseases at the borders and to protect and promote our national health security. PHAC regularly assesses and develops its strategy. Recent developments with human pathogen legislation (2) and rapid response teams (10) are examples of how PHAC continually strengthens its federal capacity to work with others in the fight against infectious diseases.

Conclusion

Multiple federal government departments work together at the Canadian border to assess people, animals, food, cargo, baggage, conveyances, containers, goods and parcels to prevent infections, toxins, vectors and potential reservoirs of infectious diseases from entering Canada. PHAC will continue to offer and advance health promotion and prevention activities, such as travel health alerts and travel health recommendations for clinicians and participates in inspections, surveillance and response activities to minimize the importation of communicable diseases into Canada.

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Conflict of interest

None

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Implementation Science

Ready to Go! Canada's new Rapid Response Team

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Abstract

The Public Health Agency of Canada (the Agency) has an important role to play in collaboration with its provincial/territorial partners to advance preparedness for emerging and re-emerging high-consequence infectious diseases. During the 2014 Ebola outbreak, the Agency established Ebola Virus Disease (EVD) Rapid Response Teams that were available to any requesting provincial/territorial jurisdiction with a laboratory confirmed case of EVD. Working with provincial and territorial officials, a Rapid Response Team Concept of Operations was developed which outlined the process for Rapid Response Team engagement as well as the suite of technical expertise available.

The Concept of Operations was refined further following a series of face-to-face advance planning meetings with individual provincial and territorial jurisdictions. This led to a consensus agreement that the Agency's Rapid Response Team should be available to support management of both confirmed and suspected EVD cases. There was also unanimous support from provincial and territorial jurisdictions that the concept and operationalization of the Agency's Rapid Response Team should be broadened to provide surge-capacity support to the provinces and territories to include any event with significant public health consequences.

The Agency will continue to engage with domestic and international partners regarding best practices to maintain a highly skilled and nimble Rapid Response Team that is operationally ready to support both domestic and international public health emergencies.

Introduction

The Public Health Agency of Canada (the Agency) has an important role to play in collaboration with its provincial and territorial partners to advance preparedness that will mitigate the effects of emerging and re-emerging high-consequence infectious diseases.

The unprecedented extent, duration and impact of the Ebola Virus Disease (EVD) outbreak in West Africa which began in the spring of 2014, provided world-wide recognition of the importance of a multi-disciplinary, international and national capacity to initiate and sustain an effective public health response over an extended period of time.

In Canada, the provinces and territories have the primary responsibility to prepare for and respond to health threats within their borders. This covers the spectrum of clinical care and treatment of individual patients to the development and implementation of policies and programs that prevent and/or mitigate the consequences of infectious diseases. At the federal level, the Agency has an important role to facilitate domestic and international collaboration and to work with other federal departments, provincial and territorial jurisdictions, non-governmental organizations and international partners to review evidence, identify best practices, coordinate a multi-jurisdictional response and provide technical resources and surge-capacity support to provinces and territories as appropriate.

Although the likelihood of an EVD case in Canada remains low, the importance of being prepared continues to be high. Accordingly, the Agency established the EVD Rapid Response Teams and engaged with all provincial and territorial jurisdictions to develop a Concept of Operations that would align with and integrate provincial and territorial EVD response protocols.

Context

In addition to supporting provincial and territorial partners, the Agency is Canada's national *International Health Regulations* (IHR) (2005) (1) focal point. Two key responsibilities for the national focal point include: to report and act on potential public health emergencies of international concern in a timely fashion, and to support public health capacity-building of partners.

Regarding the first component, the Agency works closely with provincial and territorial jurisdictions to ensure that collectively, Canada maintains its ability to report on and respond to potential public health emergencies in a timely fashion. With respect to public health capacity building, the federal government has a long history of supporting domestic and international partners. For example, the Canadian Field Epidemiology Program (formerly the Field Epidemiology Training Program) was established by Health Canada in 1975 to support provinces and territories to undertake surveillance and outbreak response activities. Since that time, the Agency has invested in additional programs to support provincial and territorial needs, including the National Microbiology Laboratory's Laboratory Liaison Technical Officers, the Canadian Public Health Service and program-specific field surveillance officers (immunization, HIV, etc.), among others.

Lessons from the Ebola outbreak

On September 30, 2014, the US Centers for Disease Control and Prevention (CDC) reported the first case of EVD diagnosed in the US—a traveller from West Africa who was subsequently hospitalized in Dallas, Texas (2). This initial case led to the identification of multiple individuals as potentially exposed, including two nurses who provided care to the initial case and who also subsequently developed EVD. The potentially exposed contacts of all three cases of EVD in the US necessitated a multi-jurisdictional public health response involving local, state and federal officials.

In October, 2014, the CDC announced the creation of CDC Ebola Response Teams to support local and state officials to respond to EVD (3). The CDC Ebola Response Teams include trained CDC medical officers, epidemiologists, infection control specialists and analysts who could be rapidly deployed to any location in the US within hours of a laboratory confirmation of Ebola infection.

To date, Canada has not had a reported case of EVD. However, EVD testing is undertaken for individuals returning to Canada from Ebola-affected countries, who subsequently develop symptoms consistent with EVD within 21 days after their arrival. The Agency's National Microbiology Laboratory works closely with provincial laboratories that conduct EVD testing, and conducts all confirmatory testing at its Winnipeg location.

During the time that EVD preparedness planning between the Agency and provincial/territorial jurisdictions was taking place, the first case of EVD in the US and the subsequent onward transmission to two health care workers was a "game-changer". Like the US, the Agency established its EVD Rapid Response Teams in October 2014 to provide rapid surge-capacity support to any provincial or territorial jurisdiction if a case of EVD occurred in Canada. The first Rapid Response Team participated in an operational exercise shortly after it was established and team members from Ottawa and Winnipeg were deployed on short notice to Nova Scotia. This exercise included an opportunity to simulate an emergency meeting between federal and provincial emergency and public health officials as well as local clinical specialists.

The Concept of Operations

Bilateral discussions with each province and territory's Chief Medical Officer of Health were critical to ensure that the EVD Rapid Response Team would meet individual provincial and territorial needs and integrate well into its response plans. Following these discussions, a draft Rapid Response Team Concept of Operations was developed and subsequently tabled at a meeting of senior federal, provincial and territorial public health officials held in November 2014.

The two key underlying principles of the initial Concept of Operations were:

1. The trigger to deploy the Rapid Response Team would be a laboratory confirmed case of EVD coupled with a call by the affected province or territory's Chief Medical Officer of Health to the Agency's Chief Public Health Officer (CPHO).
2. The Agency Rapid Response Team could offer technical expertise in any combination of six areas: epidemiology and surveillance, infection prevention and control, communications, emergency preparedness and response/logistics, biosafety, and laboratory support (**Table 1**).

Table 1: Agency Ebola Virus Disease Rapid Response Team technical support

Technical area	Nature of support to provinces and territories
Epidemiology and surveillance	Support contacting, tracing, data management, analysis and reporting.
Infection prevention and control	Provide guidance on infection prevention and control measures in hospitals and community, including patient transport, use of healthcare worker personal protective equipment (PPE), hospital waste management and decontamination.
Communications	Support coordinated risk communications, media enquiries, technical briefings and *International Health Regulations* reporting.
Emergency preparedness and response/logistics	Support provincial and territorial and mobilization of the Rapid Response Team and other Agency human resources or material assets (e.g., access to additional PPE).
Biosafety	Provide guidance on bio-containment and biosafety protocols, technical support for waste management and environmental decontamination.
Laboratory support	Support laboratories for specimen testing, including potential deployment of the mobile laboratory.

Once the Rapid Response Team Concept of Operations was accepted in principle, there was agreement that the Rapid Response Team would conduct advance planning site visits to provincial and territorial jurisdictions to further refine the Concept of Operations and tailor their approach to meet each local context and needs.

Between December 2014 and April 2015, the Agency Rapid Response Team conducted site visits with all provinces and territories. These included table top and field exercises, planning meetings and/or hospital site visits. Technical discussions between Rapid Response Team members and provinces and territories counterparts were undertaken in each of the six areas outlined in **Table 1**, enabling a customized approach to be developed with each provincial and territorial jurisdiction. For example, it was agreed the logistics and transportation requirements for both laboratory specimens and suspected cases of EVD in the territories required that Agency's Mobile Laboratory would be requested early on for a suspected case of EVD so that on-site laboratory testing could take place at the same time as arrangements for the transportation of a suspected case of EVD to a specialized treatment centre in another province.

Upon completion of the site visits, the Concept of Operations was further refined to include the following points:

- The inclusion of a senior Agency technical liaison as the Rapid Response Team Lead who would serve as the primary on-site Agency point of contact, working directly with the Chief Medical Officer of Health and other senior provincial and territorial officials. This addition was universally supported, as both strategic and operational federal, provincial and territorial collaboration would be required to manage the rapidly changing and complex demands related to an EVD case in Canada.
- The Rapid Response Team Communications Lead would likely be included as part of the initial request for Agency Rapid Response Team support to ensure a coordinated federal, provincial and territorial approach to risk communications.
- Flexibility in the initial request and deployment of the Rapid Response Team. E.g., some jurisdictions indicated that they may request immediate deployment of the full Rapid Response Team while others indicated that they would likely initially request only the Rapid Response Team Lead, with the option to request additional Rapid Response Team expertise as the situation evolved (e.g., complex contact tracing).
- The option to trigger earlier deployment of specific components of the Rapid Response Team to support management of a suspected case of EVD, e.g., the mobile laboratory.
- Expansion of the Agency Rapid Response Team approach (beyond EVD), to include all potential high-consequence public health events.

At the same time, Agency staff engaged with international partners, including the US CDC, the Pan-American Health Organization (PAHO) and the World Health Organization (WHO), to ensure the Agency's Rapid Response Team approach was consistent with like-minded regional (US, PAHO) and international (WHO) partners to maintain a deployment ready workforce to mitigate any public health event of high consequence.

Discussion

The Agency Rapid Response Team supports surge capacity in provinces and territories to manage cases of EVD and other high-consequence public health events. The Agency Rapid Response Team has evolved through close collaboration and consultation with provinces and territories. Advance planning site visits provided an opportunity to discuss various operational aspects and refined a Concept of Operations that enables the Agency's Rapid Response Team to meet unique provincial and territorial needs.

It is important to note that the Agency's Rapid Response Team could be leveraged to support a global response for similar high-consequence public health events internationally.

The Agency will continue to engage with domestic and global public health partners regarding best practices to maintain a highly skilled and nimble Rapid Response Team which is operationally ready to support both domestic and international public health emergencies.

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Conflict of interest

None.

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Regulations

Regulatory oversight of human pathogens and toxins in Canada

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Abstract

From 1994 to 2009, federal oversight of human pathogens and toxins was limited to facilities importing human pathogens and toxins into Canada under the *Human Pathogens Importation Regulations* (HPIR). This narrow focus of authority restricted the Government of Canada's ability to regulate and monitor a full range of activities, including those involving human pathogens and toxins acquired from domestic sources. In 2009, the *Human Pathogens and Toxins Act* (the Act) received Royal Assent to establish a national safety and security regime and expand oversight through a national, standardized process to verify safe and secure use of human pathogens and toxins in Canada.

The Act and the *Human Pathogens and Toxins Regulations* (the Regulations), in full force since December 1, 2015, provides legislative and statutory requirements for the comprehensive oversight of the control of human pathogens and toxins in Canada. Expanded regulation and monitoring program activities aim to reduce the risks posed by human pathogens and toxins and strengthen biosafety management systems that serve to protect the health of Canadians.

Introduction

Since 2001, there have been numerous high profile national and international laboratory accidents and incidents including exposures, laboratory-acquired infections and deliberate crimes that involve human pathogens and toxins. For example, in October 2001, letters containing anthrax were mailed to various individuals in the United States (US), resulting in five deaths (1). Approximately four months after the end of the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, a microbiology student in Singapore contracted SARS due to lapses in biosafety protocols and procedures (2). In 2011, there was an outbreak of 109 cases of *Salmonella typhimurium* in the US linked to clinical and teaching microbiology laboratories (3).

Given the limited and variable international requirements governing reporting, as well as the varied definitions of what constitutes an incident, it is likely that these events will continue to be under-reported.

Like other countries, Canada is vulnerable to the accidental or deliberate release or misuse of an agent which could result in substantial social and economic disruption and have international repercussions. Whether located in academic settings, hospitals, government departments or within private industry, many Canadian laboratories work with human pathogens and toxins, such as *Escherichia coli*, Influenza A and Listeria. If not handled properly, these agents may cause moderate illness or even death. The public health impact could be significant, and include potential outbreaks in the community, domestically or even abroad. Human pathogens and toxins can also pose national security and economic risks as a result of theft, bioterrorism or the creation of agents for which there are no countermeasures.

Since the early 2000s, there has been an international recognition of the need to enhance domestic oversight for the use of biological substances. Many countries are moving towards more stringent control of a range of activities involving human pathogens and toxins such as importation, possession, use, storage, transfer, disposal and export.

Prior to 2009, federal oversight of human pathogens and toxins in Canada was limited to facilities importing human pathogens and toxins through the HPIR. This prevented the Government of Canada from verifying the safe and secure use of human pathogens acquired from domestic sources.

In 2009, the *Human Pathogens and Toxins Act* (the Act) (4) received Royal Assent. The purpose of the Act is to establish an oversight system to protect the health and safety of the public against the risks posed by human pathogens and toxins, both domestically acquired and when they are imported into Canada. The Public Health Agency of Canada (the Agency) is the national authority for biosafety and biosecurity of human pathogens and toxins, and is responsible for their regulation under the authority of the Act and the *Human Pathogens and Toxins Regulations* (the Regulations) (5).

The Regulations came into force on December 1, 2015. Laboratories and other regulated parties now need to apply for a licence to conduct controlled activities, such as possessing, handling, using, producing, storing, permitting any person access, transferring, importing, exporting, releasing, abandoning and disposing of a human pathogen or toxin. This is a risk-based licensing framework designed to improve federal oversight of human pathogens and toxins in Canada; establish national requirements for the safe and secure handling of human pathogens and toxins that apply to all facilities that conduct controlled activities with these agents; and provide assurance that individuals who have access to a prescribed list of security-sensitive human pathogens and toxins (known as Security Sensitive Biological Agents [SSBA]) have been assessed as trustworthy and reliable.

The objective of this article is to describe the mechanisms now in place under the Act and Regulations to address the risks of human pathogens and toxins, to prevent the spread of communicable diseases and to protect the health of Canadians.

Overview of the Act and Regulations

The purpose of the Act and the Regulations is to establish a safety and security regime that will protect the health and safety of the public against risks posed by human pathogens and toxins. For example, the new licencing framework provides oversight of controlled activities with human pathogens and toxin, outlines the powers and functions as well as qualifications of a biological safety officer, and establishes security clearance requirements.

In 2009, select sections of the Act came into force to create a foundational biosafety platform. These included:

- A requirement for every person responsible for activities involving toxins listed in Schedule 1 of the Act or Risk Group 2, 3 or 4 human pathogens to be registered with the Agency.
- A ban on activities conducted with human pathogens and toxins listed in Schedule 5 (currently limited to smallpox) and an obligation to inform the Agency of an inadvertent production of Schedule 5 Prohibited human pathogens and toxins.
- A duty to take all reasonable precautions to protect the health and safety of the public when knowingly dealing with human pathogens and toxins. To help meet this current obligation, compliance with the *Canadian Biosafety Standard* (6) is recommended.

Most offence and penalty provisions are now in force as well as inspection powers that may be used to verify compliance or preventing non-compliance with the Act; inspection powers are consistent with other federal legislation.

Who this affects

The Act applies to any corporation, individual, organization, partnership or public body that knowingly conducts specified activities with human pathogens and toxins, unless exempted.

Scope

The Act does not apply to a human pathogen or toxin in an environment in which it naturally occurs if it has not been cultivated, intentionally collected or extracted (e.g., human primary blood specimens) nor to a drug in dosage form whose sale is permitted or authorized under the *Food and Drugs Act* (7) or a human pathogen or toxin contained in such a drug. The Agency has also integrated specific exemptions from the licensing requirement regarding laboratory analysis, diagnostic testing and veterinary facilities because the activities in these settings are considered low-risk.

Licensing of pathogens and toxins

Any person subject to the Act must apply for a licence. Four types of licences will be issued depending on the nature and risk of the human pathogens or toxins activities in use: Risk Group 2 (including prions and toxins), Risk Group 3, Risk Group 4 and SSBA Toxins. A licence holder (or the person who has been issued a licence under the Act) will be required to report to the Agency various events such as laboratory exposures/laboratoryacquired infections, inadvertent possession or production, gain of function (5), and theft or loss of a human pathogen or toxin. Compliance with the *Canadian Biosafety Standard* (6) will be a common licence condition, providing the minimum standard for safe use and secure laboratory containment of human pathogens, animal pathogens and toxins.

Additional requirements and licence conditions will mitigate the inherent risks posed by specific or higher risk pathogens or toxins. For example, individuals with pathogens and toxins above the trigger quantity will require a security clearance in accordance to the Act. A trigger quantity is the minimum quantity above which a toxin regulated by the Act is considered a "prescribed toxin" and therefore, a security sensitive biological agent (4). These added requirements for higher risk pathogens and toxins ensure that the Agency has comprehensive knowledge of laboratory activities and who is performing them across Canada.

Reporting requirements

Laboratory-acquired infection is a term commonly used to describe diseases associated with exposures to infectious material or toxins in the laboratory setting. However, the term laboratory exposure more accurately includes both infections and intoxications (i.e., resulting from exposure to toxins), whether symptomatic or asymptomatic in nature.

Licence holders are required to inform the Agency if they have reason to believe that an incident involving a human pathogen or toxin in their possession has, or may have caused disease in an individual. This requirement in the Act aims to increase the timeliness, accuracy and usefulness of information on laboratory exposures and laboratory-acquired infection that occur in licensed facilities across Canada. Previously, laboratory exposure and laboratory-acquired infection reporting was carried out on an ad-hoc and voluntary basis in Canada.

Requirements for laboratory exposure and laboratory-acquired infection reporting are further detailed in the *Canadian Biosafety Standard* (6) which came into effect on December 1, 2015. These involve submission of an exposure notification report and an exposure follow-up report via the same electronic portal used for licensing. The exposure notification report is to be submitted as soon as reasonably possible and consists of preliminary information about the nature of the incident and the pathogen or toxin involved. The follow-up report (due within 15 days of the exposure notification when an SSBA is involved or within 30 days of the notification when a human pathogen or toxin other than an SSBA is involved) provides further details on the exposure(s) and outcomes of the investigation, including the root causes associated with the incident.

The timely provision of information in an exposure notification report will allow the Agency to monitor developing trends in real-time and/or prompt the issuance of biosafety advisories when needed. More detailed information contained in the exposure follow-up report will enhance amendments or updates to biosafety best practices and training and will build an evidence-base that can be analyzed at the national level to inform current and future biocontainment and biosafety directions.

Over time, the move to ongoing, systematic reporting through a surveillance system will provide reliable data to establish denominators for the population at risk (overall, by sector, work types, etc.), assess exposures (prospectively), estimate exposure and laboratory-acquired infection incidence rates, provide data in real-time for mitigation and prevention and establish a robust evidence-base for decision-making to improve policy, planning and training.

Monitoring trends

The Agency will assess the surveillance information on an ongoing basis to monitor trends; inform biosafety notifications, advisories and risk-based inspection practices; aid in the development of biosafety best practices; initiate any Agency follow-up actions as/when required; and contribute to national and international data and knowledge on exposure and laboratory-acquired infection incidents.

The information generated from the national incident reporting system will be shared with stakeholders across the laboratory community of practice via an annual report on aggregate national trends. This report will summarize key findings on exposure and laboratory-acquired infection incidents and investigation findings. Since several years of data collection will be required to establish a reliable baseline for statistical comparison, initial annual reports will focus on providing a description of the reporting system and reporting rates among licence holders, establishing analysis frameworks (graphs/charts) and summarizing lessons learned and incident highlights. Once a reliable baseline has been established, trends against these estimates will provide a clearer picture of the frequency and contributing factors for incidents, including high-risk exposures and laboratory-acquired infections in Canada. As such these data will contribute to evidence-based decision-making to guide current and future biocontainment and biosafety practices.

Discussion

With the implementation of the Act and Regulations, the Agency is well positioned to mitigate the risks of an accidental or deliberate release of an infectious agent or toxin and thus the spread of a communicable disease. The Agency will have: Knowledge of who has what human pathogens and toxins in Canada; the ability to implement safety and security controls for all labs handling human pathogen and toxins whether imported or created in Canada; a robust security assessment process; and mandatory reporting requirements of incidents.

Conclusion

Through the implementation of the Act and Regulations, the human pathogen control regime promotes safe and secure laboratories while enabling Canadian public health laboratories to rapidly respond to disease outbreaksthe best and most innovative science at Canadian universities and research institutions; and maintaining a competitive edge for Canadian companies.

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Going forward, we acknowledge the preparation of our onboarding network of licence holders and biosafety officers and their continued dedication to ensuring the highest level of pathogen safety and security in Canada.

Conflict of interest

None.

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